5. 510(k) Summary

FEB 12 2014

Company:	Conventus Orthopaedics, Inc. 10200 73rd Avenue North, Suite 122 Maple Grove, MN 55369
Device Trade Name:	Conventus DRS™
Common Name:	Fracture Fixation Device
Contact:	Kent R. Lind Vice President, Quality and Regulatory Phone: (763) 515-5000 Fax: (763) 315-4980
Date Prepared:	May 30, 2013
Classification:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3020: Intramedullary fixation rod
Class:	II
Product Codes:	HRS and HSB
Indications for Use:	The Conventus DRS™ is intended for the fixation of distal radius fractures.
Device Description:	The Conventus DRS™ is an intramedullary device intended to treat distal radius fractures. The DRS is comprised of an Expandable Scaffold, Fragment Screws, and a Proximal Plate. The device remains flexible during placement, but is made rigid at the completion of the surgical implant procedure. The implant is made from titanium alloy (Ti6Al4V) and Nitinol.
Substantial Equivalence:	The Conventus DRS™ is substantially equivalent to the previously cleared Conventus DRS™ device (K102689). Testing in accordance with FDA's Guidance Document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" was performed and supports "MR Conditional" labeling for the Conventus DRS™ device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Conventus Orthopaedics, Incorporated
Mr. Kent Lind
Vice President, Quality, Regulatory, Clinical
10200 73rd Avenue North, Suite 122
Maple Grove, Minnesota 55369

Re: K131552
Trade/Device Name: Conventus DRS™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HSB
Dated: January 13, 2014
Received: January 14, 2014

Dear Mr. Lind:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K131552

Device Name: Conventus DRS™

The Conventus DRS™ is intended for the fixation of distal radius fractures.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices